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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/484,809	01/18/2000	Julio J. Santos-Munne	4204.3-US	1128

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MUNSCH, HARDT, KOPF & HARR, P.C.  
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EXAMINER

MILLER, RYAN J

ART UNIT PAPER NUMBER

2621

DATE MAILED: 01/29/2004

17

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/484,809

Applicant(s)

SANTOS-MUNNE ET AL.

Examiner

Ryan J. Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 25-34 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 25 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 January 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. The response received on January 5, 2004 has been placed in the file and was considered by the examiner. An action on the merits follows.

#### ***Response to Arguments***

2. Applicant's arguments filed with the Request for Continued examination on November 17, 2003 have been fully considered but they are not persuasive.

#### **Drawing Objections**

*Summary of Argument:* The applicant argues that the objection to the drawings should be withdrawn in light of the amendment to the specification.

*Examiner's Response:* The examiner agrees. The objection to the drawings has been withdrawn.

#### **37 CFR 1.75 Claim Objections**

*Summary of Argument:* The applicant traverses the claim objection; however, the objected to claim has been cancelled.

*Examiner's Response:* The examiner acknowledges the cancellation of the claims and presents a new 37 CFR 1.75 claim objection based on the newly added claims as presented below.

#### **35 U.S.C. 112, First Paragraph Rejections**

*Summary of Argument:* The applicant traverses the rejection; however, the rejected claims have been cancelled.

*Examiner's Response:* The examiner acknowledges the cancellation of the claims and presents a new 35 U.S.C. 112, First Paragraph rejection as presented below.

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Prior Art Rejections

**35 U.S.C. 102(b) rejections**

*Summary of Argument:* The applicant argues that new claims 27-34 are directed to measuring an anatomical feature appearing in the image using the dimensions of the virtual surgical object and that this element is absent from Peshkin et al. (U.S. Patent No. 5,799,055 A).

*Examiner's response:* The examiner disagrees. Peshkin et al. discloses such a feature as described in the rejection below.

**35 U.S.C. 103(a) rejections**

*Summary of Argument:* The applicant makes no arguments regarding the 35 U.S.C. 103(a) rejection.

*Examiner's response:* The examiner presents a similar rejection as the one presented in the previous action below.

***Election/Restrictions***

3. Applicant's election with traverse of Group II, claims 11-24 on June 5, 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is deemed proper and is therefore made FINAL.

***Specification***

4. The disclosure is objected to because of the following informalities: In the brief description of the drawings, the description of Figure 6 is actually the description of Figure 7 and the description of Figure 7 is the description of Figure 6.

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Appropriate correction is required.

***Claim Objections***

5. The following quotation of 37 CFR § 1.75(a) is the basis of objection:

(a) The specification must conclude with a claim particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention or discovery.

6. Claims 27-34 are objected to under 37 CFR § 1.75(a) as failing to particularly point out and distinctly claim the subject matter which the applicant regards as his invention or discovery. Claim 27 has two minor grammatical errors. First of all, at line 10, the claim recites the limitation “displaying in the first and second fluoroscopic images graphical representation of the virtual surgical object”. This limitation is grammatically awkward. The examiner suggests changing the limitation to read “displaying in the first and second fluoroscopic images graphical representations of the virtual surgical object”. Second, at line 12, the claim recites “adjusting the virtual surgical object such that that graphical representations”. This limitation is also grammatically awkward. The examiner suggests changing this limitation to read “adjusting the virtual surgical object such that graphical representations”.

Claims 28-34 are objected to as depending from an objected to claim.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 27-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

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art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The invention as originally filed has three embodiments. The first embodiment, described on page 2, lines 3-26, page 7, line 24 – page 10, line 9, and in Fig. 4, discloses a method of determining the dimensions of an anatomical feature by determining the distance of a line specified by at least two points in a fluoroscopic image. The second embodiment, described on page 3, lines 1-30, page 7, line 28 – page 13, line 9, and in Fig. 6, discloses a method of displaying and manipulating a graphical representation of a virtual surgical object in a fluoroscopic image. The third embodiment, for determining the velocity of an object, is not pertinent in this rejection. Claim 27 is drawn to the second embodiment. However, the last step of the claim, “providing a dimension of the anatomical feature of interest based on the one or more dimensions of the virtual surgical object” is not supported by the original disclosure as being a step executed by the second embodiment. As can be seen in Fig. 6 (i.e. corresponding to the second embodiment), the first four steps of the claim are clearly disclosed. However, the step of “providing a dimension of the anatomical feature of interest based on the one or more dimensions of the virtual surgical object” is not shown, nor is it described anywhere in the specification. This step most nearly corresponds to the step 112 of Fig. 4, which would make the claim a mix of the disclosed embodiments that does not have literal support in the original disclosure. However, step 112 of Fig. 4 determines the dimension of an anatomical feature of interest based on the length of a line passing through two points on the anatomical feature of interest. This embodiment does not determine the dimension of an anatomical feature of interest based on the dimensions of a virtual surgical object. Nowhere in the disclosure is such a step

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mentioned or described. Since there is no support for the final limitation of this claim in the disclosure, it will be assumed that this limitation is not present for examination purposes.

Claims 28-34 are rejected as depending from a rejected claim.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 27-29 and 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Peshkin et al. (U.S. Patent No. 5,799,055 A).

As applied to claim 27, Peshkin et al. discloses a computer-assisted method for determining a dimension of an anatomical feature, the method comprising: displaying a first fluoroscopic image taken of an anatomical feature of interest from a first angle (see Figs. 1, 3a, and column 5, lines 14-29: The reference describes using a fluoroscope to take an image of a patient's body and then displaying the image on graphics monitor 48 (i.e. displaying a first fluoroscopic image taken of an anatomical feature of interest from a first angle).) and a second fluoroscopic image of the anatomical feature of interest taken from a second angle (see Figs. 1, 3b, and column 5, lines 30-32: The reference discloses obtaining a second image of the patient's body from a different angle and displaying it on graphics display 50 from an angle different from the first image.), the first and second images being registered with respect to a common three-dimensional coordinate system (see column 5, lines 24-29 and lines 35-42: The reference describes registering each of the images to the three-dimensional coordinates of the fiducials in

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the image.); defining at a known position and orientation in the three-dimensional coordinate system, with in the area of interest of the patient, a virtual surgical object, the surgical object having one or more dimensions (see column 5, lines 46-49: The reference describes receiving a users input to select the position, length, and angles (i.e. defining in the three-dimensional coordinate system) of a virtual guidewire (i.e. an object). The user input of the position, length, and angles corresponds to receiving indications of the position of the object with respect to the first and second fluoroscopic images.); displaying in the first and second fluoroscopic images graphical representation of the virtual surgical object projected into the first and second fluoroscopic images (see column 5, lines 49-54: The reference describes drawing a segment that represents the virtual guidewire (i.e. a graphical representation of the object) and that the projected virtual guidewire corresponds geometrically to the same three-dimensional segment in space.); and adjusting the virtual surgical object such that graphical representations of the virtual surgical object fit the anatomical area of interest shown in at least one of said first and second images (see column 5, lines 60-61: The reference describes that the user can change the length (i.e. adjust the dimension) of the virtual guidewire (i.e. the object)).

As applied to claim 28, Peshkin et al. discloses selecting an implant or surgical device for insertion into said patient based at least in part on said determined dimension of the anatomical feature (see column 3, lines 14-22: The reference describes that the process can be used to select a screw based on the information obtained in the image.).

As applied to claim 29, Peshkin et al. discloses that the surgical object comprises a three-dimensional object (see column 3, lines 14-22: The reference describes that the surgical object can be a screw or biopsy needle both of which are three-dimensional objects.).



As applied to claim 31, which is representative of claims 33 and 34, Peshkin et al. discloses that the adjusting step comprises adjusting a dimension of the virtual surgical object to fit the anatomical feature of interest shown in at least one of said first and second images (see column 6, lines 5-8: The reference describes adjusting the coordinates and orientation (i.e. adjusting the dimensions) of the virtual guidewire (i.e. the virtual surgical object) to correspond to an entry point (i.e. fit the anatomical feature of interest).).

As applied to claim 32, Peshkin et al. discloses that adjusting a dimension of the virtual surgical object includes adjusting the virtual surgical objects shape (see column 5, lines 60-61: The reference describes that the user can change the length (i.e. adjust the dimension) of the virtual guidewire (i.e. the object). If the length of the virtual guidewire is changed then the shape is also changed.).

### ***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Peshkin et al. (U.S. Patent No. 5,799,055 A) and Alt (U.S. Patent No. 6,159,142 A). The arguments as to the relevance of Peshkin et al. in the rejection of claims 27 and 28 above are incorporated herein.

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Claim 30 calls for the object to represent a stent. A stent is absent from Peshkin et al. but is clearly shown in Alt (see column 1, lines 57-64: The describes a process of implanting a stent under fluoroscopic observation).


It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify Peshkin et al. by adding the stent of Alt because the use of fluoroscopic imaging when implanting stents is widespread. Therefore, a method for planning this surgery through the use of fluoroscopic images and virtual stents is very important for increasing the safety and reliability of such procedures.

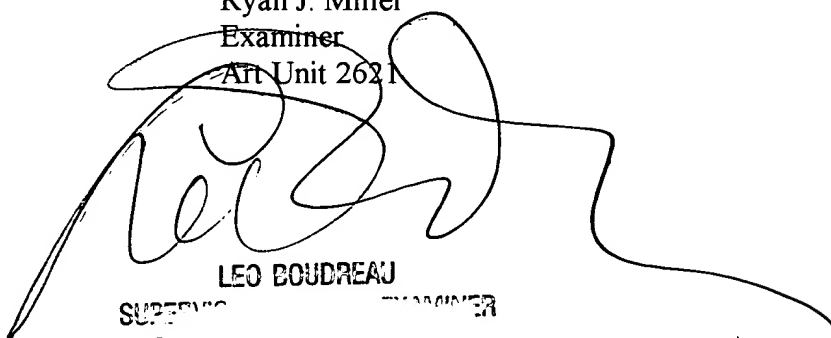
### *Conclusion*

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan J. Miller whose telephone number is (703) 306-4142. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo H. Boudreau can be reached on (703) 305-4706. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-4750.

  
Ryan J. Miller

Ryan J. Miller  
Examiner  
Art Unit 2621  
  
LEO BOUDREAU  
SUPERVISOR  
TECHNICAL